KenKyu

Clinical Case Reports, Research & Trials 5: 10-16 (2020)

Research ISSN: 2581-6756

The Evaluation of BV® Blue Test Kit in the Diagnosis of Bacterial Vaginosis in Comparison with Nugent Score

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Received June 22, 2020; **Accepted** July 10, 2020; **Published** July 13, 2020

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Abstract

Aim: To evaluate the sensitivity, specificity and predictive value of the BV Blue® test kit in the diagnosis of bacterial vaginosis using Nugent score as the diagnostic standard.

Methodology: This was a prospective cross sectional study on 158 women that was carried out in Obstetrics and Gynecology Department, Hospital Putrajaya. Two vaginal samplings were collected for each subjects, in which first sample will be tested for BV blue test and the second sample for Gram stain.. The Gram-stained slides were assessed using Nugent scoring.

Results: The sensitivity of BV blue test was 82% with high specificity of 100% compared to the results of the Nugent's score. The negative predictive value (NPV) of BV blue was 92.4% and the positive predictive value (PPV) was 100% .

Conclusion: BV blue test is a simple, rapid and valid test for BV blue to diagnose bacterial vaginosis. It does not require microscopy or skilled laboratory technician for interpretation which is usually time consuming. Both diagnosis and treatment can be made during the first visit. This will save time and cost for both the practitioner and the patients. It will also reduce the need of having additional laboratory resources in that particular health care center.

Introduction

Bacterial vaginosis (BV) is a clinical syndrome resulting from replacement of the normal lactobacilli in the vagina with high concentrations of anaerobic microorganisms such as Gardnerella vaginalis, Prevotella, Peptostreptococcus, Bacteroides and Mobilincus. [1] The prevalence of bacterial vaginosis varies according to country, ethnic and socio economic status.

A variety of tests are available in detecting the changes of vaginal ecology that have been used for diagnosis of bacterial vaginosis. Amsels's criteria and Nugent scoring can be used in diagnosis of bacterial vaginosis. Both require interpretation with the given clinical scenario and both are time consuming. Amsel criteria was found to be moderately sensitive (78%) but has high specificity of 88%, meanwhile gram stain has an excellent sensitivity (95%) but with lower specificity (58%).[5] Gram stain method is reproducible and reliable for the diagnosis of bacterial vaginosis, however Amsel criteria require confirmation by Gram stain method. [5]

Until today, attempt to diagnose bacterial vaginosis is hardly made because it requires laboratory evaluation and subsequent follow up. Thus in our local settings where patient's load and compliance is a major issue, most clinicians tend to start

treatment empirically. The request of gold standard Nugent score for the diagnosis of BV is hardly made in our practice. While Amsel's criteria is too time consuming and requires 4 set of test, therefore it is rarely done. In the end, neither most clinicians know what they are treating nor do the patients know what they are suffering from.

The detection of bacterial vaginosis is important as many clinical studies had shown significant correlation between bacterial vaginosis and complications such as miscarriage, preterm labor, PPROM, chorioamniotis and pelvic inflammatory disease. The women with bacterial vaginosis are at increased risk of chorioamniotis with the release of pro-inflammatory cytokines, which can lead to preterm birth. [2] It is found in studies that bacterial vaginosis occurs more common among women with pelvic inflammatory disease and presence of isolated microrganisms associated with bacterial vaginosis in the upper genital tract. [7]

The BV blue test is an enzymatic activity test. It is used to detect sialidase enzymatic activity in vaginal fluid specimens. Sialidase is an enzyme produced by pathological microorganism which causes bacterial vaginosis. The test is simple, rapid and can be done by unskilled person and even at rural setup. Studies done showed BV blue test was found to have high sensitivity of 90.3% and high specificity of 96.6% compared to Gram stain results by Nugent score [6].

Until today, there is only one local study that has evaluated the role of BV blue test kit in the diagnosis of bacterial vaginosis. The results show high sensitivity of 100% and specificity of 98.3% [1]. The objective of this study is to evaluate the sensitivity, specificity and predictive value of the BV Blue® test kit in the diagnosis of bacterial vaginosis using Nugent score as the diagnostic standard.

Methodology

This was a prospective cross sectional study that was carried out in Obstetrics and Gynecology Department, Hospital Putrajaya from 1st April 2015 to 28th February 2016. The study has obtained approval from national Medical Research and Ethics Committee (MREC).

158 women who presented or referred to Obstetrics and Gynaecology Department in Hospital Putrajaya were recruited prospectively. Patients who had oral or vaginal antimicrobial treatment within past 2 weeks, were menstruating or having vaginal bleeding, had engaged in vaginal sexual intercourse or had vaginal douched within 72h prior to test were excluded from the study.

After obtaining a written consent, a questionnaire was given to each subject to collect demographic data, presenting complaints, symptoms, medical history as well as past obstetrics and gynaecology history.

A pelvic examination was then performed by a trained medical officer. Two vaginal samplings were collected from each patient. Both samplings were taken from lower one-third of vaginal wall in which first sample was tested for BV blue test and the second sample for Gram stain.

One of the vaginal swabs was collected from the lower one-third of the vagina wall via aseptic technique. The swab was then placed into the BV Test Vessel and the mixture gently swirl. The BV Test Vessel containing the swab was let to stand for 10 minutes between 17 and 37oC (62.6-98.6oF). One drop of Developer Solution was then added to the BV Test Vessel containing the swab and the mixture gently swirl. Results were read immediately and documented as positive result if a blue or green colour in the BV Test Vessel or on the head of the swab; or negative result: a yellow colour in the BV Test Vessel.

Then, a sterile speculum lubricated with water only was used to see the condition of the cervix and nature of the discharge. The second vaginal swab was obtained from lower one-third of the vagina wall via aseptic technique and was then placed on a glass slide for gram staining in the microbiology laboratory. The samples were coded with specimen number and were read by a single medical laboratory technologist who was blinded from BV Blue test results. The Gram-stained slides were assessed using Nugent scoring as attached in Appendix 1.

The subjects with positive BV blue test were immediately treated with oral Metronidazole 400 mg TDS for 10 days. Meanwhile the subjects with negative BV blue test but Nugent score suggestive of bacterial vaginosis were called for follow up at our outpatient clinic for treatment as mentioned above.

Data was analysed using IBM SPSS package version 21.0. Laboratory- based Nugent Gram staining evaluation will be used to diagnose BV. Subjects' characteristics were analysed using freguency(n) with percentage, mean with standard deviation or median with interquartile range as appropriate. Sensitivity, specificity, positive and negative predictive values were stratified to all participated women.and measured using standard calculation for diagnostic accuracy.

Results

In this study, a total of 158 women subjected. Demographic data of women was shown in Table 1. Their mean age was 31 (SD, 4.4). The vast majority of participant was Malays, followed by Chinese, Indian and others in order. Of these, 126 (80%) were pregnant women.120 out of 158 women (75.9%) were employed and 35 of them (22.2%) were homemakers.

Of all the women, more than half were asymptomatic (90,57%). Only 31 (19.6%) complained of abnormal vaginal discharge and 2 (1.3%) of them had foul smelly discharge. While, 9 (5.7%) presented with lower abdominal pain, 15(9.5%) with leaking liquor and 11(7%) with vaginal bleeding (Table 2).

Pelvic examination revealed only small number of women had vaginal discharge typical of bacterial vaginosis 12(7.6%), while 36 (22.8%) has curdy like discharge suggestive of vaginal candidiasis and only 2(1.3%) had foul smelly vaginal discharge. Some of these women may have more than one symptom or sign. (Table 2)

Out of 158 women recruited in this study, forty, 40 (25%)of the women had a positive BV Blue test. While, 49 (31%) women were diagnosed to have bacterial vaginosis based on gram stain with Nugent's score between 7 and 10. The sensitivity of BV blue test was high (82%) with high specificity of 100% compared to the results of the Nugent's score. The negative predictive value(NPV) of BV blue was 92.4% and the positive predictive value(PPV) was 100%.

Characteristics	**n (%)**	**OR (95% CI)**
Age (mean, SD)	31 (4.4)	
Race		
-Malay	147 (93.0)	
-Chinese	6 (3.8)	
-Indian	4(2.5)	
-Others	1 (0.6)	
Education (n=155, missing=3)		
-Primary school	0 (0)	
-Secondary school	42 (26.6)	
-College/diploma	43 (27.2)	
-University (degree/master/PhD)	70 (44.3)	
Occupation (n=155, missing=3)		
-Homemaker	35 (22.2)	
-Employed	120 (75.9)	
Parity		

0	47 (29.7)	
-1	47 (29.7)	
-2	41 (25.9)	
-≥3	23 (14.6)	

Table 1: Demographic data (N=158)

Clinical features	n (%)	OR (95% CI)
SYMPTOMS		
-Asymptomatic	90 (57.0)	
-Abnormal vaginal discharge	31 (19.6)	
-Foul smelly vaginal discharge	2 (1.3)	
-Lower abdominal pain	9 (5.7)	
-Leaking liquor (PPROM)	15 (9.5)	
-Vaginal bleeding	11 (7.0)	
SIGNS		
-yellowish or grayish vaginal discharge	12 (7.6)	
-thin milky vaginal discharge	23 (14.6)	
-Curd like discharge	36 (22.8)	
-foul smelly vaginal discharge	2 (1.3)	
-inflamed cervix	13 (8.2)	

Table 2: Clinical features of study participants (N=158)

Discussion

Significant correlation between bacterial vaginosis (BV) and complications such as miscarriage, preterm labor, PPROM, chorioamniotis and pelvic inflammatory disease in many clinical studies show the importance of bacterial vaginosis detection (2). There has been an increase of interest in diagnosis and treatment of bacterial vaginosis due to these serious complications. In this study, the efficacy of BV blue test in diagnosing bacterial vaginosis was evaluated.

In this study, BV was diagnosed in 40 out of the 158 patients (25%) using BV blue test. Lower rates (22%, 21%) were observed by previous studies (3, 6 respectively) using BV blue test for BV diagnosis. Moreover, higher rate was observed by Khatoon et al., (8) who diagnosed BV in 60.8% of cases.

While, the results of this study revealed that from 158 patients, 49 (31%) were diagnosed as bacterial vaginosis by Nugent score. Some studies reported lower BV prevalence rates such as Madhivanan et al. (9) that found the prevalence of BV is 19%. Others reported higher BV incidence rates such as Lowe et al., (10), who reported 42% of cases had bacteral vaginosis, and Thulker et al., (11), who diagnosed 53.8% cases of vaginitis as bacterial vaginosis.

The BV blue test has shown excellent performance with 100% specificity in comparison with Gram stain (Nugent's score). It is also highly sensitive with 82% sensitivity with a PPV of 100% and a NPV of 92.4%. Our study was in agreement with Myziuk et al (6) that found sensitivity and specificity of BV Blue test compared to Gram stains results by Nugent score were 90.3% and 96.6% respectively. The result of our study

also supports a local study, Kampan et al (1) who conducted a prospective, cross sectional study on 151 women on diagnosis of bacterial vaginosis using BV blue test that found its sensitivity of 100% and specificity of 98.3%.

The BV blue test detects elevated vaginal fluid sialidase activity, an enzyme produced by bacterial pathogens associated with BV including Gardnerella vaginalis, Bacteroides spp., Prevotella spp., and Mobilincus spp. (2). Sialidases are of considerable importance in women's health in that they have been shown to act in a way that enhances the attachment of these pathogens to mucosal vaginal tissue thereby allowing the invasion of the bacteria and destruction of the mucosal tissue. This is done through the breakage of sialic acid residue from sialylglyconjugates.

The emergence of a bedside test kit, BV blue test opens a new horizon in the diagnosis and treatment of bacterial vaginosis. BV blue test is a rapid bedside test with about 1 minute hands-on-time and 10 minutes read-time. This simple test shows instant color change that provides clear, easy-to-read results. This test does not require gram staining, microscopy or skilled laboratory technician for interpretation which is usually time consuming.

Therefore, the BV blue test is an excellent procedure for rapid BV diagnosis compared with conventional diagnostic methods by Nugent score. This test can be performed easily in peripheral hospitals or in any setups lacking laboratory facilities. Even in settings which conventional diagnostic methods and expertise are available, it still benefits outpatient department or any bedside procedure by its rapidity. By using BV blue test, the clinicians know what they are dealing with. Thus, patients can be counselled about the disease and treated appropriately. Therefore, it can help to effectively diagnose and prevent various sequelaes associated with bacterial vaginosis such as preterm labour, premature rupture of membrane, fetal prematurity, and pelvic inflammatory disease etc. A single BV Blue cost is very small. It is almost , negligible when compared to the cost of further follow up and long term burden of the sequlae of the disease.

Conclusion

BV blue test is an excellent point of care test. It is highly sensitive and specific with excellent both PPV and NPV. It is al so the most cost effective test available currently. It reduces the need for laboratory support and additional follow up for the patients. This point of care testing allows bacterial vaginosis to be eradicated at the first consultation. Hence will reduce the sequele and complications related to this pathology.

Conflict Of Interest

We declare that we have no conflict of interest.

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